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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,298	08/18/2003	Ann de Wees Allen	ALL-T101D1	4203

23557 7590 05/12/2008

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EXAMINER	
ROYDS, LESLIE A	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
05/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/643,298	ALLEN, ANN DE WEES	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6-9 and 12-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-9 and 12-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-3, 6-9 and 12-15 are presented for examination.

In view of the Appeal Brief filed on February 8, 2008, **PROSECUTION IS HEREBY REOPENED**. New grounds of rejection are set forth below.

To avoid abandonment of the application, Appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then Appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614

Claims 1-3, 6-9 and 12-15 are pending and under examination.

Applicant's arguments, presented in the Appeal Brief filed February 8, 2008, have been fully considered and are persuasive regarding the application of Winitz et al. (U.S. Patent No. 3,697,287) etc. as prior art. Accordingly, the rejections as set forth against claims 1-3, 6-9 and 12-15 over such references have been withdrawn. Rejections not reiterated from the final Office Action are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 103 (New Grounds of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudman et al. ("Growth Hormone Treatment of Frailty in Men Over 60", *New England Journal of Medicine*, 1990) in view of Fulks et al. ("Effects of Insulin, Glucose, and Amino Acids on Protein Turnover in Rat Diaphragm", *J. Biol. Chem.*, 250(1); 1975:290-298) and further in view of Dudrick et al. (U.S. Patent No. 5,026,721; 1991).

Rudman et al. teaches various agents that are capable of enhancing the release of growth hormone, such as arginine (para. bridging col.2, p.4-col.1, p.5), vitamin B5 and choline (p.5, col.1, l.9-11 of the penultimate paragraph; p.6, col.1, last paragraph), as well as boron (para.1-2, p.6, col.2). Rudman et al. further teaches that a release of growth hormone, in turn, increases the muscle to fat ratio of the body and stimulates the immune system, as does arginine itself (p.4, col.1, penultimate paragraph). Rudman et al. also discloses that arginine was capable of speeding healing and increased resistance to cancer cells in experimental animals (p.4, col.1, penultimate paragraph) and acknowledges the efficacy of vitamin C in protecting tissue from damage by superoxide radicals produced by macrophages to kill bacteria (p.4, para. bridging cols.1-2).

Rudman et al. fails to disclose the concomitant use of L-leucine, L-isoleucine and L-valine (claims 1 or 6) or the use of L-arginine *per se* (claims 1 or 6).

Fulks et al. discloses a study of branched chain amino acids (i.e., leucine, isoleucine and valine) in regulating protein turnover in rat diaphragm muscle, wherein it was demonstrated that addition of the

branched chain amino acids alone decreased protein catabolism as compared to the remaining amino acids (i.e., all but the branched chain amino acids), which did not alter the rate of protein breakdown significantly (col.1, para.3, p.295). Fulks et al. further teaches that the branched chain amino acids were also capable of stimulating protein synthesis at least to the same extent as a complete mixture of amino acids and further discloses that the branched chain amino acids also function to increase protein synthesis (col.2, para.2, p.295). Still further, Fulks et al. discloses that leucine, isoleucine and valine play a crucial role in regulating net protein balance in muscle and additionally teaches that the effects of leucine, isoleucine and valine on protein synthesis appeared to be approximately additive. Fulks et al. further notes that the factors that promoted synthesis and inhibited degradation in the incubated diaphragm have long been recognized as important for muscle growth *in vivo* (col.1, para.2, p.297).

One of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to administer the arginine, vitamin B5 and choline components of Rudman et al. together with leucine, isoleucine and valine for use in a mammalian subject for the purpose of stimulating muscle growth, since each compound was known to have efficacy in increasing muscle mass. Thus, the suggestion to make such a combination flows logically from the very fact that each was known in the prior art to have (1) the same therapeutic utility and (2) were explicitly demonstrated (i.e., Rudman et al.) or reasonably expected (i.e., Fulks et al.) to function to achieve this therapeutic utility *in vivo* in a mammal, and, in turn, raises the reasonable expectation of success that this combination of compounds, when combined, would have, at minimum, additive, if not synergistic, muscle mass increasing effects when combined and used in a mammal.

As stated in *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980): "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. *In re Susi*, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); *In re Crockett*, 47

CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960)."

Furthermore, regarding the use of the L-form of each of arginine, leucine, isoleucine and valine, Dudrick et al. is cited for its teaching of an amino acid nutritional supplement for the purpose of enhancing physical performance (abstract), particularly an improvement in muscle growth and strength (col.2, l.11-20), containing a mixture of biologically active amino acids, including arginine, leucine, isoleucine and valine (abstract, col.3, l.34-47), which are preferably in the L-form, since the L-form is considerably more biologically active than the D-form (col.3, l.30-33).

One of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to administer the L-form of arginine, leucine, isoleucine and valine (rather than the D-form) in the composition of Rudman et al. modified by Fulks et al. because the L-form of such amino acids was known to be more biologically active than the D-form, as evidenced by Dudrick et al. Such a person would have been clearly motivated to do so in order to maximize the biological activity (and, thus, efficacy) of the composition for increasing muscle mass in a mammalian subject.

Claims 1-3 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudman et al. ("Growth Hormone Treatment of Frailty in Men Over 60", *New England Journal of Medicine*, 1990) in view of Fulks et al. ("Effects of Insulin, Glucose, and Amino Acids on Protein Turnover in Rat Diaphragm", *J. Biol. Chem.*, 250(1); 1975:290-298) and Dudrick et al. (U.S. Patent No. 5,026,721; 1991) and further in view of Boynton et al. (U.S. Patent No. 5,087,624; Issued 1992, Priority to 1987) and Remington's Pharmaceutical Sciences (Sixteenth Edition, 1980; pages 669-671).

Rudman et al., Fulks et al. and Dudrick et al. as applied above.

The cited references fail to teach the concomitant use of chromium (claims 3 and 9) or the dosage and route of administration (claims 2-3 and 7-9).

Boynton et al. is cited for its teaching of the use of chromic picolinate, a combination of chromium with picolinic acid, at a dose to provide about 10 to about 500 mcg of chromium per day, which can be used as an anabolic agent in animals (including both human and non-human mammals) to increase the lean body mass and to concomitantly decrease the percentage of body fat (col.4, l.43-68).

One of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to combine the chromic picolinate compound of Boynton et al. (i.e., a chromium compound as required by instant claims 3 and 9) with the L-arginine, L-leucine, L-isoleucine, L-valine, vitamin B5 and choline components suggested by Rudman et al. in view of Fulks et al. and Dudrick et al. for use in a mammalian subject for the purpose of stimulating muscle growth, since each compound was known to have efficacy in increasing muscle mass. Thus, the suggestion to make such a combination flows logically from the very fact that each was known in the prior art to have (1) the same therapeutic utility and (2) were explicitly demonstrated (i.e., Rudman et al. and Boynton et al.) or reasonably expected (i.e., Fulks et al.) to function to achieve this therapeutic utility *in vivo* in a mammal, and, in turn, raises the reasonable expectation of success that this combination of compounds, when combined, would have, at minimum, additive, if not synergistic, muscle mass increasing effects when combined and used in a mammal.

As stated in *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980): "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. *In re Susi*, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960)."

Regarding the presently claimed amounts or route of administration to stimulate muscle growth with the claimed combination of active agents, the determination of the optimum amounts or the optimal route of administration of the active agents would have been a matter well within the purview of, and

prima facie obvious to, one of ordinary skill in the art at the time of the invention. Such a determination would have been made in accordance with a variety of factors, such as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, the amount that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed specific amounts are not seen to be inconsistent with that which would have been determined by, and well within the routine skill of, the skilled artisan.

Additionally, the concentration of the active ingredients is a result-effective variable, i.e., a variable that achieves a recognized result, and, therefore, the determination of the optimum or workable dosage range would be well within the practice of routine experimentation by the skilled artisan, absent factual evidence to the contrary, and, further, absent any evidence demonstrating a patentable difference between the compositions used and the criticality of the amount(s). In further support thereof, Applicant's attention is directed to the MPEP at §2144.05, which states, "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges in the optimum combination of percentages...Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." Although the present claims are directed to gram and milligram concentrations, such a motivation is nonetheless relevant.

Additionally, it is noted that the skilled artisan would have considered the amount of active agent(s) to be administered, the tolerability to the regimen (i.e., toxicological or adverse effects) and patient compliance with the regimen to determine the optimum route of administration (i.e., oral, intravenous, etc.). Please see Remington's, at pages 669-670, which teaches various routes of

administration (e.g., oral, sublingual, parenteral, intravenous, etc.) well known in the art at the time of the present invention, the use of any of which would have been *prima facie* obvious to, and within the routine knowledge of, the skilled artisan, absent factual evidence to the contrary.

Claims 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cerra et al. (U.S. Patent No. 4,780,475; 1988) in view of Rudman et al. ("Growth Hormone Treatment of Frailty in Men Over 60", *New England Journal of Medicine*, 1990) and further in view of Fulks et al. ("Effects of Insulin, Glucose, and Amino Acids on Protein Turnover in Rat Diaphragm", *J. Biol. Chem.*, 250(1); 1975:290-298) and Dudrick et al. (U.S. Patent No. 5,026,721; 1991).

Cerra et al. teaches that patients undergoing abnormal metabolic stress states induced by, e.g., sepsis, experience decreased fat mobilization and utilization and glucose utilization due to hormonal changes precipitated by stress (col.1, l.14-22). Under such conditions, Cerra et al. teaches that an extremely high and rapid rate of muscle protein catabolism occurs, which results in the liberation of branched chain amino acids, namely, isoleucine, leucine and valine from the bound protein state to the free amino acid state (col.1, l.22-27). Cerra et al. further discloses that the free branched chain amino acids are then readily available to be further catabolized to yield energy to help satisfy the energy deficit caused by metabolic stress (col.1, l.27-30). To solve this problem, Cerra et al. teaches a composition of amino acids comprising L-isoleucine, L-leucine and L-valine with other essential and non-essential amino acids for significantly improving nitrogen retention by decreasing muscle protein catabolism and markedly improving protein synthesis in stressed patients, such as septic patients (col.1, l.61-col.2, l.33).

Cerra et al. fails to teach the use of L-arginine, vitamin B5 or choline (claim 12) or vitamin C as an immune system stimulator (claim 14) or the use of L-arginine, L-isoleucine, L-leucine and L-valine without other amino acids (claim 12).

Rudman et al. teaches various agents that are capable of enhancing the release of growth

hormone, such as arginine (para. bridging col.2, p.4-col.1, p.5), vitamin B5 and choline (p.5, col.1, l.9-11 of the penultimate paragraph; p.6, col.1, last paragraph), as well as boron (para.1-2, p.6, col.2). Rudman et al. further teaches that a release of growth hormone, in turn, increases the muscle to fat ratio of the body and stimulates the immune system, as does arginine itself (p.4, col.1, penultimate paragraph). Rudman et al. also discloses that arginine was capable of speeding healing and increased resistance to cancer cells in experimental animals (p.4, col.1, penultimate paragraph) and acknowledges the efficacy of vitamin C in protecting tissue from damage by superoxide radicals produced by macrophages to kill bacteria (p.4, para. bridging cols.1-2).

One of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to administer L-isoleucine, L-leucine and L-valine, which are known to inhibit muscle protein catabolism and improve protein synthesis in stressed patients, such as septic patients as evidenced by Cerra et al., with arginine, vitamin B5 and choline, which are known to increase muscle mass and stimulate the immune system as evidenced by Rudman et al., for the purpose of inhibiting muscle protein catabolism caused by bodily stress as a result of the sepsis (see Cerra et al.), as well as for the purpose of stimulating the immune system and building muscle mass in such a patient with muscle loss as a result of the catabolism caused by sepsis. Such a person would have been motivated to do so for the purpose of inhibiting further muscle loss and to replace lost muscle mass in patients prone to muscle protein catabolism, such as a septic patient, as well as to enhance function of the immune system to fight the infection causing sepsis in such a patient by administering the immune stimulating agents arginine, vitamin B5 and choline.

Moreover, one of ordinary skill in the art at the time of the invention would have also found it *prima facie* obvious to further include vitamin C into such a combination of agents because a septic patient with bacteria in the bloodstream would have been reasonably expected to have an overabundance of superoxide radicals in the body as a result of the macrophages killing the bacteria causing the sepsis (as

evidenced by Rudman et al.). Such a person would have been motivated to do so in order to protect body tissue from the damage that occurs as a result of superoxide radicals.

Still further, though Cerra et al. discloses the use of additional amino acids in the composition disclosed by this reference, one of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to administer L-leucine, L-isoleucine and L-valine with arginine but in the absence of other essential or non-essential amino acids because Fulks et al. teaches that branched chain amino acids alone decreased protein catabolism as compared to the remaining amino acids (i.e., all but the branched chain amino acids), which did not alter the rate of protein breakdown significantly (col.1, para.3, p.295). Fulks et al. further teaches that the branched chain amino acids were also capable of stimulating protein synthesis at least to the same extent as a complete mixture of amino acids and further discloses that the branched chain amino acids also function to increase protein synthesis (col.2, para.2, p.295). In view of such a teaching, such a person skilled in the art would have been motivated to administer the combination of L-leucine, L-isoleucine and L-valine with arginine in the absence of the other essential and non-essential amino acids disclosed in Cerra et al. because, as evidenced by Fulks et al., the branched chain amino acids were more effective in decreasing protein catabolism than all other amino acids combined but the branched chain amino acids.

Furthermore, regarding the use of the L-form of each of arginine, leucine, isoleucine and valine, Dudrick et al. is cited for its teaching of an amino acid nutritional supplement for the purpose of enhancing physical performance (abstract), particularly an improvement in muscle growth and strength (col.2, l.11-20), containing a mixture of biologically active amino acids, including arginine, leucine, isoleucine and valine (abstract, col.3, l.34-47), which are preferably in the L-form, since the L-form is considerably more biologically active than the D-form (col.3, l.30-33).

One of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to administer the L-form of arginine, leucine, isoleucine and valine (rather than the D-form) in

the asserted combination therapy because the L-form of such amino acids were known to be more biologically active than the D-form, as evidenced by Dudrick et al. Such a person would have been clearly motivated to do so in order to maximize the biological activity (and, thus, efficacy) of the composition for increasing muscle mass, decreasing protein catabolism and stimulating immune function in a mammalian subject.

Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cerra et al. (U.S. Patent No. 4,780,475; 1988) in view of Rudman et al. ("Growth Hormone Treatment of Frailty in Men Over 60", *New England Journal of Medicine*, 1990) and further in view of Fulks et al. ("Effects of Insulin, Glucose, and Amino Acids on Protein Turnover in Rat Diaphragm", *J. Biol. Chem.*, 250(1); 1975:290-298) and Dudrick et al. (U.S. Patent No. 5,026,721; 1991) and Remington's Pharmaceutical Sciences (Sixteenth Edition, 1980; pages 669-671).

Cerra et al., Rudman et al., Fulks et al. and Dudrick et al. as applied above.

The cited references fail to teach the dosage and route of administration (claims 13 and 15).

Regarding the presently claimed amounts or route of administration to stimulate an immune response with the claimed combination of active agents, the determination of the optimum amounts or the optimal route of administration of the active agents would have been a matter well within the purview of, and *prima facie* obvious to, one of ordinary skill in the art at the time of the invention. Such a determination would have been made in accordance with a variety of factors, such as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, the amount that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed

specific amounts are not seen to be inconsistent with that which would have been determined by, and well within the routine skill of, the skilled artisan.

Additionally, the concentration of the active ingredients is a result-effective variable, i.e., a variable that achieves a recognized result, and, therefore, the determination of the optimum or workable dosage range would be well within the practice of routine experimentation by the skilled artisan, absent factual evidence to the contrary, and, further, absent any evidence demonstrating a patentable difference between the compositions used and the criticality of the amount(s). In further support thereof, Applicant's attention is directed to the MPEP at §2144.05, which states, "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges in the optimum combination of percentages...Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." Although the present claims are directed to gram and milligram concentrations, such a motivation is nonetheless relevant.

Additionally, it is noted that the skilled artisan would have considered the amount of active agent(s) to be administered, the tolerability to the regimen (i.e., toxicological or adverse effects) and patient compliance with the regimen to determine the optimum route of administration (i.e., oral, intravenous, etc.). Please see Remington's at pages 669-671, which teaches various routes of administration well known in the art at the time of the present invention. In particular, one of skill in the art would have been motivated to employ an intravenous route of administration as evidenced by Remington's, since intravenous administration provides a rapid response and can be more accurately delivered (p.670), as well as the fact that it avoids first-pass metabolism or inactivation within the digestive tract, which significantly decreases the pharmacologic efficacy of the active compound.

Conclusion

Rejection of claims 1-3, 6-9 and 12-15 is proper.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

May 4, 2008

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614